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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/715,172 11/20/00 SUZUKI

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002292 HM22/0620  
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EXAMINER

DO, P

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/715,172

Applicant(s)

Suzuki et al.

Examiner

Pensee T. Do

Art Unit

1641



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Apr 19, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above, claim(s) 11-18 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-10 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 1-18 are subject to restriction and/or election requirements.

## Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of group I, claims 1-10 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that searching both groups I and II would not present an undue burden on the examiner. This is not found persuasive because the methods of groups I and II are unrelated and furthermore the method of group II has additional steps such as observing the size of and/or changes in human medullasin content in the blood obtained in said step (b). This step alone would require additional search and thus would present an undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

2. The abstract of the disclosure is objected to because it contains more than one paragraph. Correction is required. See MEP. § 608.01(b).

### ***Claim Rejections - 35 U.S.C. § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is indefinite. The recitation 'characterized' is not a conventional claim language. Furthermore, it is unclear as to what is encompassed by this term.

In claim 8, please change "captur" to --capture--.

***Claim Rejections - 35 U.S.C. § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki et al. (Clinica Chimica ACTA(Dec 15 1988) 178(2) 193-204) in view of Voet et al. (Biochemistry 1990).

Aoki teaches an enzyme immunoassay of medullasin in peripheral blood. Medullasin is located in granulocytes (leukocytes) and bone marrow cells. The medullasin protein is extracted and purified for antibody generation in rabbits. A solid support is coated with an anti-medullasin IgG antibody. The coated bead is incubated with an amount of diluted peripheral blood to bind the medullasin. After incubation, the complex is incubated with an enzyme labeled conjugate and the amount of activity of the label is determined (pages 195-196).

However, Aoki does not teach using an aqueous liquid for lysing cells.

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Voet teaches isolation of protein located in cytosol of cells by osmolysis. Isolation of proteins requires that the protein is in solution. Therefore, cells are suspended in a hypotonic solution and under the influence of osmotic forces, water diffuses into the more concentrated intracellular solution thereby causing the cells to swell and burst thus releasing the protein of interest (page 76).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Aoki by suspending cells comprising the protein of interest into a buffer solution having an osmotic pressure sufficient to allow osmolysis of the cell as taught in the method of Voet because Voet teaches that osmolysis of cells for protein isolation is conventional in the art and is efficient, simplest, and gentlest method known.

7. Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki in view of Voet as applied to claims 1, 8-10 above and further in view of Lapicola (US 4,745,071).

See discussion on Aoki and Voet set forth above. These references differ from the invention in failing to teach a specific buffer or lysing agent for cells.

Lapicola teaches a method for the volumetric differentiation of blood cell types. The reagents used comprise a diluent with an osmolality that can be adjusted to 320 +/-5 milliosmoles with sodium chloride. The level of the diluent can be set at a level other than 320 +/- 5 milliosmoles. The organic buffers comprise various acids and alcohols (col. 5, lines 35-55). A surfactant such as quaternary ammonium salts comprising three alkyl short chain groups may be

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added to the diluent as a lysing agent. The studies of the quaternary ammonium salts in blood show lysing of various leukocyte populations (col. 6, lines 32-68).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate in the modified method of Aoki the buffers comprising lysing reagent as taught in the method of Lapicola because Lapicola teaches that quaternary salts disclosed in the diluent buffers were capable of lysing leukocyte populations in blood. Therefore, one would have been motivated to incorporate a solution comprising a surfactant such as a quaternary salt for lysing of leukocytes for the quantification of medullasin activity in a blood sample.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri. from 7 a.m. to 3 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Pensee T. Do  
Patent Examiner  
June 15, 2001



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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06/17/01